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EXAMINER	
LUM, LEON YUN BON	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/965,683	POPE, EDWARD J. A.	
	Examiner	Art Unit	
	Leon Y. Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 14 October 2005 is acknowledged and has been entered. In addition, the amendments to the specification, filed 13 June 2005, has also been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. In claim 6, lines 1-2, the phrase "the light source is connected by conductive electrodes" is vague and indefinite. The specification does not provide disclosure on how conductive electrodes are connected to the light source and it is unclear s to whether the conductive electrodes connect the light source to another embodiment and what that embodiment is, or whether the conductive electrodes connect the plurality of sensor light sources to each other.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 33, 7, and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroy et al (US 5,252,294) in view of Hamblen (US 4,948,214).

Kroy et al reference teaches a structure 1 (i.e. chip) with a CCD array in the same arrangement as a plurality of microcavities 2, as indicated by the CCD cells 17' (i.e. plurality of sensors, each of which contains at least one optical detector), and a pen 16 suitable for applying light irradiation through windows 17 into chambers 2 (i.e. light source). See column 2, lines 35-38; column 6, lines 58-63, and Figures 1 and 10.

However, Kroy et al reference fails to teach that each of the sensors contains at least one light source.

Hamblen reference teaches an array of LEDs 25 in optical cement 24, each of the LEDs emitting to a corresponding chamber 21 and separated by opaque separators 17, in order to provide simultaneous light emission to an array of chambers with embodiments to prevent cross talk with adjacent light guides. See column 2, lines 29-55; column 4, lines 4-10 and Figures 1 and 3.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Kroy et al with an array of LEDs 25 in optical cement 24, each of the LEDs emitting to a corresponding chamber 21 and separated by opaque separators 17, as taught by Hamblen, in order to provide simultaneous light emission to an array of chambers with embodiments to prevent cross talk with adjacent light guides. The single light source of Hamblen may cause inadvertent light-induced activation in adjacent microcavities. However, by incorporating the LED array and opaque separators of Kroy et al, into the chip of Hamblen, each microcavity within the chip can be activated simultaneously and no microcavity will have contamination by activation from light emissions directed at adjacent microcavities. Therefore, Hamblen provides motivation for combining the LED array with the device of Kroy et al by disclosing an arrangement of LEDs that allow for more efficient assaying through simultaneous and accurate light emissions. In addition, one of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including an array of LEDs, as taught by Hamblen, in the device of Kroy et al, since Kroy et al teach light irradiation through windows into individual chambers, and the LEDs of Hamblen are

designed to provide a source of light into individual chambers though an optical material.

With regards to claim 7, Kroy et al reference teaches that the sensors can be silicon (i.e. semi-conducting material). See column 5, lines 33-34.

With regards to claims 13-16, Kroy et al reference teaches substances including immobilized antibody and antigen (i.e. bioactive material, protein, antibody), wherein substances are examined for immune reactions and the substances can be provided with fluorescent markings (i.e. fluorescence-labeled antibody). See column 1, lines 9-24 and column 4, lines 5-9 and 31-32.

8. Claims 3 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroy et al (US 5,252,294) in view of Hamblen (US 4,948,214) as applied to claim 33 above, and further in view of Berndt et al (US 5,281,825).

Kroy et al and Hamblen references have been disclosed above, but fail to teach that the light source is an electroluminescent material (claim 3).

Berndt et al reference teaches phosphor particles in an ELL as a light source, wherein ELLs can be used to illuminate samples contained in a 96-well assay simultaneously, in order to measure the concentration of an analyte by utilizing luminescence lifetimes. See column 3, lines 6-26; column 6, lines 53-56; column 10, lines 62-65; and Figure 4.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Kroy et al and Hamblen with phosphor particles in an

ELL as a light source, wherein ELLs can be used to illuminate samples contained in a 96-well assay simultaneously, as taught by Berndt et al, in order to measure the concentration of an analyte by utilizing luminescence lifetimes. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including phosphor containing ELL as a light source, as taught by Berndt et al, in the device of Kroy et al and Hamblen, since Kroy et al and Hamblen teach an array of light sources directed into a chip with individual chambers, and the ELLs taught by Berndt et al can be directed simultaneously at wells in a 96-well plate, which is one type of chip with individual chambers.

With respect to claim 6, Berndt et al reference teaches a first electrode 20 and a second electrode 21 that sandwiches the phosphor particles (i.e. light source is connected by conductive electrodes). See column 10, lines 62-67 and Figure 4.

9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kroy et al (US 5,252,294) in view of Hamblen (US 4,948,214) as applied to claim 33 above, and in further view of Berndt et al (US 5,281,825) and Hosokawa et al (US 5,121,029).

Kroy et al and Hamblen references have been disclosed above, but fail to teach that the light source is an organic electroluminescent material.

Berndt et al reference teaches ELL as a light source, wherein ELLs can be used to illuminate samples contained in a 96-well assay simultaneously, and wherein the ELL contains phosphor particles, in order to measure the concentration of an analyte by utilizing luminescence lifetimes. See column 3, lines 6-26; column 6, lines 53-56;

column 10, lines 62-65; and Figure 4. However, Berndt et al reference fails to teach that the ELL is an organic electroluminescent material.

Hosokawa et al reference teaches an electroluminescence device that emits light with an organic element, in order to permit greatly reduced voltages to be applied. See column 1, lines 10-35.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Kroy et al and Hamblen with ELL as a light source, wherein ELLs can be used to illuminate samples contained in a 96-well assay simultaneously, and wherein the ELL contains phosphor particles, as taught by Berndt et al, in order to measure the concentration of an analyte by utilizing luminescence lifetimes. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including phosphor containing ELL as a light source, as taught by Berndt et al, in the device of Kroy et al and Hamblen, since Kroy et al and Hamblen teach an array of light sources directed into a chip with individual chambers, and the ELLs taught by Berndt et al can be directed simultaneously at wells in a 96-well plate, which is one type of chip with individual chambers.

It would also have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Kroy et al, Hamblen, and Berndt et al with an electroluminescence device that emits light with an organic element, as taught by Hosokawa et al, in order to permit greatly reduced voltages to be applied. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including an organic element, as taught by Hosokawa et al, in the device of

Kroy et al, Hamblen, and Berndt et al, since Kroy et al, Hamblen, and Berndt et al teach electroluminescent elements that emit light, and the organic element taught by Hosokawa et al is one type of electroluminescent element.

10. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kroy et al (US 5,252,294) in view of Hamblen (US 4,948,214) as applied to claim 33 above, and in further view of Berndt et al (US 5,281,825) and Waymouth (US 5,095,245).

Kroy et al and Hamblen references have been disclosed above, but fail to teach that the light source is an inorganic electroluminescent material.

Berndt et al reference teaches ELL as a light source, wherein ELLs can be used to illuminate samples contained in a 96-well assay simultaneously, and wherein the ELL contains phosphor particles, in order to measure the concentration of an analyte by utilizing luminescence lifetimes. See column 3, lines 6-26; column 6, lines 53-56; column 10, lines 62-65; and Figure 4. However, Berndt et al reference fails to teach that the ELL is an inorganic electroluminescent material.

Waymouth reference teaches an electroluminescent device that is preferably composed of inorganic materials, including phosphor materials such as zinc sulfide, in order to provide an EL device having higher efficiency and improved light output. See column 2, lines 40-42 and column 4, lines 4-35.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Kroy et al and Hamblen with ELL as a light source, wherein ELLs can be used to illuminate samples contained in a 96-well assay

simultaneously, and wherein the ELL contains phosphor particles, as taught by Berndt et al, in order to measure the concentration of an analyte by utilizing luminescence lifetimes. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including phosphor containing ELL as a light source, as taught by Berndt et al, in the device of Kroy et al and Hamblen, since Kroy et al and Hamblen teach an array of light sources directed into a chip with individual chambers, and the ELLs taught by Berndt et al can be directed simultaneously at wells in a 96-well plate, which is one type of chip with individual chambers.

It would also have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Kroy et al, Hamblen, and Berndt et al with an electroluminescent device that is preferably composed of inorganic materials, including phosphor materials such as zinc sulfide, as taught by Waymouth, in order to provide an EL device having higher efficiency and improved light output. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including an inorganic element, as taught by Waymouth, in the device of Kroy et al, Hamblen, and Berndt et al, since Kroy et al, Hamblen, and Berndt et al teach electroluminescent elements that emit light, and the organic element taught by Hosokawa et al is one type of electroluminescent element.

11. Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroy et al (US 5,252,294) in view of Hamblen (US 4,948,214) as applied to claim 33 above, and further in view of Aktik (US 4,866,499).

Kroy et al and Hamblen references have been disclosed above, but fail to teach that the detector is composed of amorphous silicon (claim 8).

Aktik reference teaches a hydrogenated amorphous-silicon photosensitive diode element, wherein the photosensitive elements can be placed in an array, in order to overcome disadvantages of CCD devices including a large number of processing steps for fabrication and poor sensitivity for short wavelengths of light. See column 1, lines 26-49 and column 2, lines 3-9.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Kroy et al and Hamblen with a hydrogenated amorphous-silicon photosensitive diode element, as taught by Aktik, in order to overcome disadvantages of CCD devices including a large number of processing steps for fabrication and poor sensitivity for short wavelengths of light. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including an amorphous silicon photosensitive diode, as taught by Aktik, in the device of Kroy et al and Hamblen, since Kroy et al and Hamblen teach optical detector arrays, and the photosensitive elements of Aktik also detect optical signals and can be placed in an array format.

With respect to claims 9-11, Aktik reference teaches that the photosensitive diode element is sensitive to blue and ultraviolet wavelengths (i.e. tuned to respond to a specific wavelength range of light; tuned to a different wavelength range of light). See column 5, lines 9-11. Aktik reference does not explicitly teach that each detector is tuned to a different wavelength range of light. However, since the photosensitive diode

elements are disclosed as having the capability of detecting a plurality of wavelengths, and Kroy et al and Hamblen reference teaches separate detectors for individual chambers, the instant references encompass the situation wherein one photosensitive element detects blue wavelength and another photosensitive element detects ultraviolet wavelengths, and reads on the limitations of claims 10-11 in being able to be "tuned to a different wavelength range of light". In claim 11, the phrase "and the output of these detectors produces a spectra" is considered an intended use of the chip and does not provide patentable weight to the claimed invention.

12. Claims 17-19, 23-24, and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroy et al (US 5,252,294) in view of Hamblen (US 4,948,214) as applied to claim 33 above, and further in view of Pope (SPIE, 1992, vol. 1758, pp. 360-371).

Kroy et al and Hamblen references have been disclosed above, and Kroy et al reference additionally teaches that substances in the cavities can be gels. See column 4, lines 35-36. However, Kroy et al and Hamblen fail to teach that each sensor is coupled to a porous silica gel microsphere doped with an organic dye.

Pope reference teaches fluorescent organic rhodamine dyes incorporated into microspheres, wherein the microspheres are silica gel-based, in order to produce chemical sensors based on optically active molecules incorporated into the microspheres. See page 361, 1st-2nd paragraph and page 363, 2nd paragraph.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Kroy et al and Hamblen with fluorescent organic dyes incorporated into silica microspheres, as taught by Pope, in order to produce chemical sensors based on optically active molecules incorporated into the microspheres. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including fluorescent organic dyes incorporated into silica microspheres, as taught by Pope, in the device of Kroy et al and Hamblen since Kroy et al teach a structure that can hold gels in the cavities and detect fluorescence, and the rhodamine-doped silica gel-based microspheres of Pope are one type of gel with fluorescence properties.

13. Claims 20-22, 25-27, and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroy et al (US 5,252,294) in view of Hamblen (US 4,948,214) as applied to claim 33 above, and further in view of Torobin (US 4,743,545) and Torobin (US 4,671,909).

Kroy et al and Hamblen references have been disclosed above. Kroy et al reference additionally teaches that substances in the cavities can be gels and that the structure can be used for cell and immunity research and medical research. See column 1, lines 37-44 and column 4, lines 35-36. However, Kroy et al and Hamblen references fail to teach that each sensor is coupled to a porous silica gel microsphere doped with a protein or enzyme, and fail to teach that each sensor is coupled to a porous silica gel microsphere doped with a living cell.

Torobin ('545) reference teaches hollow porous microspheres encapsulating biocatalysts including cells, enzymes, and antibodies, in order to provide biocatalysts to quantify biological substances or perform biotech processes including protein binding assays and catalyzing enzyme and bacterial biochemical reactions, wherein a gel-forming material immobilizes the biocatalyst within the microspheres. See column 1, lines 26-35 and column 28, line 63 to column 29, line 20. However, Torobin ('545) reference fails to teach that the gel-forming material is silica gel.

Torobin ('909) reference teaches silica sol gel in microspheres, in order to reduce the void content and increase the surface area of support in the pores in which it is desired to place a semipermeable membrane that seal the microsphere pores, but can selectively allow passage of nutrients and oxygen into the hollow microspheres and allow passage of biologically produced products and/or waste products out of the hollow microspheres. See column 3, lines 2-6; column 11, line 52 to column 12, line 19; and Figures 6A-B.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Kroy et al and Hamblen with hollow porous microspheres encapsulating biocatalysts including cells, enzymes, and antibodies, as taught by Torobin ('545) in order to provide biocatalysts to quantify biological substances or perform biotech processes including protein binding assays and catalyzing enzyme and bacterial biochemical reactions. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including microspheres encapsulated with cells, enzymes, and antibodies, as taught by Torobin

('545) in the device of Kroy et al and Hamblen since Kroy et al and Hamblen teach a structure with cavities that can hold a gel for cell, immunity, and medical research, and the microspheres of Torobin ('535) include a gel-forming substance and provide antibodies for protein binding assays, which are components in immunity and medical research.

In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Kroy et al, Hamblen, and Torobin ('545) with silica sol gel in microspheres, as taught by Torobin ('909), in order to reduce the void content and increase the surface area of support in the pores in which it is desired to place a semipermeable membrane that seal the microsphere pores, but can selectively allow passage of nutrients and oxygen into the hollow microspheres and allow passage of biologically produced products and/or waste products out of the hollow microspheres. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including silica sol gel in microspheres, as taught by Torobin ('909) in the device of Kroy et al, Hamblen, and Torobin ('545), since Kroy et al, Hamblen, and Torobin ('545) teach a structure with cavities that can hold a gel, and the silica sol gel of Torobin ('909) are one type of gel substance.

Response to Arguments

14. On pages 14-16 of the Remarks, filed 13 June 2005, Applicant traversed the rejection of claims 2, 7, and 13-16 under 35 U.S.C. 103(a) as being obvious over Kroy

et al in view of Hamblen. Applicant has cancelled claim 2 and added new claim 33 that does not differ in scope from claim 2. Specifically, Applicant argues "Kroy does not teach that each sensor includes at least light source." See page 14, 2nd full paragraph.

Applicant's arguments have been fully considered, but are not persuasive. Although Applicant is correct in stating that Kroy et al do not teach a device in which each sensor has a light source, the rejection of claim 2 was an obviousness rejection that relied upon Hamblen reference to teach this limitation. Hamblen provides teaching of an LED array, each LED corresponding to an individual channel. The motivation for combining the LED array of Hamblen with the sensor array chip of Kroy et al is to provide the capability of simultaneous light emission to directed at specific microcavities while preventing light contamination to adjacent microcavities. Since Kroy et al teach that the microcavities are exposed to light through a window, and Hamblen teaches that the LED emissions can penetrate optical materials, there is a reasonable expectation of success in combining the LED array of Hamblen with the chip of Kroy et al. Since Applicant has not traversed the rejection of claim 2 on the merits of Hamblen reference, Applicant's argument against the rejection is not persuasive.

In light of the fact that newly added claim 33 contains essentially the same embodiments and claim language, the previous rejection of claim 2 is hereby applied to claim 33 and maintained.

With respect to dependent claims 3-32, since Applicant relies only upon the statement "Kroy does not teach that each sensor includes at least light sensor" to

traverse all dependent claims, Applicant's arguments are also not found convincing for claims 3-32, and the rejections made in the previous Office Action are maintained.

Conclusion

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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